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Essential but expensive? The World Health Organization, access to medicines, and human rights

Abstract

Now widely accepted as a component of the international human rights framework, the concept of access to medicines nonetheless continues to generate controversial questions as to its scope and application. Through critical analysis of relevant documentary materials, this article seeks to explore the conjunction between human rights and the list of essential medicines compiled biennially by the World Health Organization (WHO) in the particular context of the recent expansion of this list to embrace a number of very costly medical interventions. Such extension is intended to stimulate access in the long run, but the expense of such medicines may limit accessibility in the short term, as governments struggling to ensure the sustainability of health systems choose to allocate finite resources elsewhere. The article therefore examines the compatibility of limitations to access on grounds of lack of affordability, with international human rights obligations. It focuses especially upon Article 12 of the International Covenant on Economic, Social and Cultural Rights, but also considers other human rights which may be engaged.

1. Introduction

Access to medicines is now regarded as an indispensable component of the right to the highest attainable standard of health under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR),¹ although it also connects to other human rights, as will be discussed subsequently. A distinction is drawn between medicines deemed as ‘essential’ and those which are not, the former being those which are defined by the World Health Organization Action Programme on Essential Drugs’.² Provision of these, as distinct

¹ Human Rights Council (HRC), ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (13 September 2006) UN Doc A/61/338, para. 40.

² CESCR, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant) (2000) UN Doc E/C.12/2000/4, para. 12(a).

from medicines which are not so listed, is specified as a core obligation by General Comment No. 14 issued by the UN Committee on Economic, Social and Cultural Rights.³ Classification of medicines as ‘essential’ by the World Health Organization (WHO) is thus a significant act from the perspective of international human rights.⁴

The focus of the present analysis is upon the ‘unprecedented development’⁵ of the inclusion in the most recent two iterations of the list of essential medicines of a number of very high-cost technologies, ranging from US\$60,000 to US\$100,000 per treatment.⁶ This action is likely to generate difficult issues of affordability for large numbers of states,

³ *ibid*, para. 43(d).

⁴ It should be noted, however, that the status of General Comments remains a matter of contention. As Keller and Grover observe, ‘reactions to General Comments have ranged from regarding them as “authoritative interpretations” of treaty norms, to “broad, unsystematic, statements which are not always well founded, and are not deserving of being accorded any particular weight in legal settings”’: H. Keller and L. Grover, ‘General Comments of the Human Rights Committee and their legitimacy’, in H. Keller and G. Ulfstein, eds., *UN Human Rights Treaty Bodies: Law and Legitimacy* (Cambridge University Press, 2012)

(for an example of the latter position in relation to General Comment No. 14, see Observations by the United States of America on “The Right to Health, Fact Sheet No. 31” <www.state.gov/documents/organization/138850.pdf> accessed 2 November 2018. Following Gostin, this article views both General Comments and Special Rapporteur reports as ‘interpretive instruments’ which clarify the nature of state obligations in international human rights law: see L. Gostin, *Global Health Law* (Harvard University Press 2014) 68; and further Statement by Mr. Zeid Ra’ad Al Hussein, United Nations High Commissioner for Human Rights, at the International Law Commission, 21 July 2015, <www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16254&LangID=E> accessed 2 November 2018 (‘human rights treaty bodies... play an important role in establishing the normative content of human rights and in giving concrete meaning to individual rights and state obligations’).

⁵ UN Secretary General’s High-Level Panel on Access to Medicines, *Report: Promoting Innovation and Access to Health Technologies* (United Nations 2016) 16.

⁶ Costs cited in K. Perehudoff, B. Toebe and H. Hogerzeil, ‘A human rights-based approach to the reimbursement of expensive medicines’ (2016) 94 *Bulletin of the World Health Organization* 935, 935.

including high-income economies, raising fresh and difficult questions concerning compliance with international human rights obligations relating to medicines. This article will explore this issue through an examination of relevant treaty provisions, reports of treaty bodies and special rapporteurs, together with material on essential medicines produced by WHO and other United Nations actors.

Following a brief account of the development of the list, the article examines, first, the rationale for, and implications of, the recent extension of the list in this direction, and, second, the extent to which a failure by states to provide access to expensive medicines of this type – an increasingly likely eventuality in light of their significant cost – may constitute a violation of international human rights obligations.

2. The Essential Medicines List

2.1 Development of the list

Initiated by a report by the Director-General in 1975, the WHO's strategy to identify a limited range of safe and efficacious medicines sought to address the 'urgent need to ensure that the most essential drugs are available at a reasonable price and to stimulate research and development to produce new drugs adapted to the real health requirements of developing countries'.⁷ The Organization was concerned both that significant resources were being expended upon 'expensive drugs that are only marginally useful, or even totally irrelevant to the solution of countries' main health problems, whereas large segments of the population are in urgent need of essential drugs for disease control and primary health care';⁸ and with the phenomenon of 'drug-dumping', whereby medicines which had failed to meet regulatory standards in the developed world were offered for sale in lower-income countries, thus exacerbating health inequalities between states.

WHO published its first list, then entitled the *Model List of Essential Drugs*, in 1977 (the 'essential medicines' designation was adopted in 2002). It contained 204 items, and was divided – as remains the case, although the number of medicines listed has almost doubled over time – between 'core' medicines, currently described as 'minimum medicine needs for a

⁷ WHO, 'Prophylactic and Therapeutic Substances: Report by the Director-General' (3 April 1975) A28/11, 2.

⁸ *ibid*, 1.

basic healthcare system... the most efficacious, safe and cost-effective medicines for priority conditions’, and those which are ‘complementary’, ie ‘essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed’; in cases where there is uncertainty as to the designation, this list may also include medicines ‘on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings’.⁹ It should be noted that the designation of a medicine on one list rather than the other ‘does not imply that only core medicines should be procured by the public system, while complementary medicines are optional’,¹⁰ and no distinction is drawn between the lists as a matter of international human rights law.

Responsibility for creation of the list rests with the Expert Committee on Selection and Use of Medicines, the members of which are appointed by the Director General, based upon equitable geographical representation, gender balance and professional competencies. The list is updated on a biennial basis, and the current iteration (2017) is the twentieth. A separate list of medicines for children up to twelve years of age was first issued in 2007.

Consistent with the initial objective of rational selection of medicines appropriate to the needs of a particular population, the WHO emphasised in 1977 that lists of essential drugs should be drawn up locally, but that its “guiding” or “model” list should be understood as a tentative identification of a “common core” of basic needs which has universal relevance and applicability’.¹¹ This juxtaposition of local implementation and universal standard-setting remains a characteristic of the Organization’s essential medicines strategy and carries implications for the nature of human rights obligations which will be explored subsequently in this article. Nonetheless, the WHO observes that existence of ‘the Model List has led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity’.¹² This suggests that, notwithstanding the need for local adaptation and

⁹ WHO Expert Committee on the Selection and Use of Essential Medicines, ‘The Selection and Use of Essential Medicines’ (WHO Technical Report Series 1006, 2017) 424.

¹⁰ N. Magrini et al, ‘Tough Decisions on Essential Medicines in 2015’ (2015) 93 Bulletin of the World Health Organization 283, 283.

¹¹ WHO Expert Committee on the Selection of Essential Drugs, ‘The Selection of Essential Drugs’ (WHO Technical Report Series 615, 1977) 8.

¹² WHO, ‘Essential Medicines’ <www.who.int/medicines/services/essmedicines_def/en/> accessed 10 May 2018. See also WHO Expert Committee on the Selection and Use of

implementation, ‘the essential medicines concept... has taken on somewhat of a moral universality, as a thing that has acquired enough stakeholders and commonsensical status that it is increasingly difficult to argue against’;¹³ such medicines may be said to possess a particular status as global public goods:¹⁴

2.2 Evolution of the list

The concept of an ‘essential medicine’ has evolved over time. The 1977 list defined an essential medicine as one ‘of utmost importance, basic, indispensable and necessary for the health and needs of the population’.¹⁵ The present definition, applied from the 2002 list onward, is that such medicines ‘are those that satisfy the priority health care needs of the population’.¹⁶ It is clear that the latter is significantly broader in scope, and probably vaguer.¹⁷

Similarly, the basis on which medicines are chosen for inclusion on the list has altered. Initially, ‘the selection of medicines was determined by the experience of the members of the Expert Committee. There was no systematic search and reporting of evidence to support the selection’,¹⁸ with applications for inclusion being made as a consequence of

Essential Medicines, ‘The Selection and Use of Essential Medicines’ (WHO Technical Report Series 914, 2002) 38.

¹³ J. Greene, ‘Making Medicines essential: the emergent centrality of pharmaceuticals in global health’ (2011) 6 *Biosocieties* 28.

¹⁴ See S. Moon, ‘Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health’ (2009) 2 *Global Health Governance* 1. As noted below (n 61), more than four out of five countries globally currently have national medicines lists.

¹⁵ WHO Expert Committee on the Selection of Essential Drugs (n 11) 9.

¹⁶ WHO Expert Committee on the Selection and Use of Essential Medicines (n 12) 15.

¹⁷ See V. Marks, S. Latham, and S. Kishore, ‘On Essentiality and the World Health Organization’s Model List of Essential Medicines’ (2017) 83 *Annals of Global Health* 637, 639.

¹⁸ See R. van den Ham, L. Bero, and R. Laing, *The World Medicines Situation 2011: Selection of Essential Medicines* (WHO 2011) 3.

representations made by WHO staff or pharmaceutical companies.¹⁹ In light of concerns as to lack of specificity and transparency of rationales for inclusion, an evidence-based approach, which entailed systematic analysis of efficacy, safety and comparative cost-effectiveness considerations, was adopted from 2001 onwards.²⁰

In principle, the new approach meant that a high absolute cost of a medicine was not a factor which precluded inclusion of a medicine on the list if it met other selection criteria.²¹ While patented medicines had not *per se* been excluded from inclusion on the original WHO list, the initial acknowledgment that ‘cost represents a major selection criterion’ had led, in practice, to avoidance of most patented medicines,²² but from 2001, ‘affordability has been changed from a precondition for listing an essential medicine to a consequence that must be managed after the decision to list’.²³ Despite this alteration, it remained the case until recently that few patented medicines were included: it was estimated in 2010 that 95% of the medicines listed were off patent.²⁴

A further change has been in the scope of medicines covered, with an increasing number of the medicines listed being targeted at non-communicable diseases. Thus, the 1977 list contained six cancer medicines, while the 2015 list contained 46.

3. Recent developments: ‘repositioning’ the list

This latter development points towards a shift in priorities in WHO’s essential medicines strategy. As noted previously, the 1975 Report of the Director-General had envisaged that the creation of a list of essential medicines would primarily be of benefit to

¹⁹ See R. Laing et al, ‘25 Years of the WHO Essential Medicines Lists: Progress and Challenges’ (2003) 361 *Lancet* 1723, 1724.

²⁰ WHO Secretariat, ‘WHO Medicines Strategy: Revised Procedure for Updating WHO’s Model List of Essential Drugs: Report by the Secretariat’ (7 December 2001) EB109/8.

²¹ *ibid*, para. 15.

²² WHO Expert Committee on the Selection of Essential Drugs (n 11) 12. There were some exceptions, such as praziquantel for the treatment of various parasitic worm infections.

²³ Magrini et al (n 10) 283.

²⁴ E. Siew-Kuan Ng, ‘Global Health and Development: Patents and Public Interest’ in T. Pogge, M. Rimmer and K. Rubenstein, eds., *Incentives for Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press 2010) 116.

developing countries.²⁵ In fact, while the first list noted that ‘there are convincing justifications for WHO to propose “model” or “guiding” lists of essential drugs as a contribution to solving the problems of those Member States whose health needs far exceed their resources and which may find it difficult to initiate such an endeavour on their own’,²⁶ the criteria for selection initially adopted were not specifically oriented towards medicines in such countries, prompting opposition from pharmaceutical companies concerned that it would lead to the replacement of branded products by generic medicines worldwide.²⁷ In consequence, the second iteration of the list made clear that the concept of essential medicines was restricted to developing countries,²⁸ and until very recently, there has been a continuing focus upon ‘resource-constrained settings, and... the most basic medicines’.²⁹ The emphasis upon communicable diseases, which have traditionally been regarded as prevalent primarily in developing countries,³⁰ is indicative of this initial focus.

The inclusion of a greater number of treatments for communicable diseases is, in part, explicable by the growing incidence of such conditions in low- and middle-income countries.³¹ However, it also reflects WHO’s contemporary perception of essential medicines as a ‘global concept’, captured in its claim that ‘once thought of as relevant only in resource-constrained settings, the WHO Model Lists are now seen as equally relevant to high-, middle- and low-income countries’.³² On this basis today’s ‘essential medicines are not cheap

²⁵ WHO (n 7).

²⁶ WHO Expert Committee on the Selection of Essential Drugs (n 11) 8. See also A. Wertheimer and T. Santella, ‘Innovation and the WHO’s essential medicines list: Giving credit where credit is due’ (2007) 3 *Research in Social and Administrative Pharmacy* 137.

²⁷ Greene (n 13) 19-20.

²⁸ *ibid*, 20.

²⁹ A. Gray et al, ‘Essential Medicines are still essential’ (2015) 386 *Lancet* 1601, 1601.

³⁰ IMS Institute for Health Informatics, *Understanding the Role and Use of Essential Medicines Lists* (IMS Health Incorporated 2015) 5.

³¹ The WHO estimates that more than 75% of global deaths from noncommunicable disease occur in such countries: see WHO, *Factsheet: Noncommunicable Diseases* (1 June 2018).

³² WHO (n 12). See also H. Hogerzeil, ‘The Concept of Essential Medicines: Lessons for Rich Countries’ (2004) 329 *British Medical Journal* 1169.

medicines for poor people in developing countries. They are the most cost-effective treatment for a given condition’.³³

The extension of essential medicines into a concept with global reach is further underlined by the inclusion in the 2015 and 2017 lists of a number of high-cost patented drugs for the treatment of hepatitis C, multidrug resistant tuberculosis, pre-exposure prophylaxis to prevent HIV infection, and cancer. There appear to be two, related, rationales for this step.

First, these are conditions which are identified as strategically significant. In accordance with UN Sustainable Development Goal 3 (to ‘ensure healthy lives and promote well-being for all at all ages’),³⁴ the WHO has called for the elimination of viral hepatitis as a major public health threat,³⁵ for a reduction in global deaths from tuberculosis of 90%,³⁶ and to ‘end the AIDS epidemic’,³⁷ all by 2030. Cancer has also long been a strategic priority,³⁸ and has recently been described as ‘a growing public health concern’ in light of a projected 50% increase in incidence globally by 2030.³⁹

Secondly, and more generally, ‘access to safe, effective, quality and affordable medicines... for all’ – which is a constituent element of achieving universal health coverage⁴⁰ – is seen as a ‘global concern’ by the Organization.⁴¹ Similarly, the availability and accessibility of medicines worldwide has been identified as a priority by the UN General

³³ A. Chapman, *Global Health, Human Rights and the Challenge of Neoliberal Policies* (Cambridge University Press 2016) 207.

³⁴ UN General Assembly, *Transforming our world: the 2030 Agenda for Sustainable Development*, 21 October 2015, A/RES/70/1.

³⁵ See WHO, *Global Health Sector Strategy on Viral Hepatitis 2016-2021* (WHO 2016) 9.

³⁶ WHO, *The End TB Strategy* (WHO 2015) 5.

³⁷ WHO, *Global Health Sector Strategy on HIV 2016-2021* (WHO 2016) 23.

³⁸ See World Health Assembly, ‘Cancer Prevention and Control’, WHA 58.22 (25 May 2005)

³⁹ World Health Assembly, ‘Cancer prevention and control in the context of an integrated approach’, WHA 70.12 (31 May 2017).

⁴⁰ Target 3.8 of the Sustainable Development Goals (n 34).

⁴¹ WHO, ‘Addressing the global shortage of, and access to, medicines and vaccines: Report by the Director-General’, A71/12 (19 March 2018) para. 5.

Assembly,⁴² with the UN Secretary-General also convening a High-Level Panel in 2015 to ‘review and assess proposals and to recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies’.⁴³

Inclusion of the high-cost treatments is rooted in scientific evidence of their clinical efficacy, safety, and comparative cost-effectiveness. Reflecting the changing definition of ‘essential’ which was outlined previously, these are therefore identified as the best medicines to address the ‘priority health care needs’ of sufferers of those conditions which have been identified as being of particular global significance. However, WHO has also explicitly acknowledged that it is seeking to ‘reposition the Essential Medicines List... to explore and emphasize roles that the EML could play in improving global access to and selection and use of medicines’,⁴⁴ stating that listing constitutes ‘an important step in making them more affordable and more widely accessible’.⁴⁵ Listing of such medicines thus also represents a component of a strategy to address problems of access to affordable medicines worldwide.⁴⁶ It therefore sits alongside other WHO initiatives such as the institution of a Fair Pricing Forum, which is ‘seen as a first step towards identifying an actionable agenda towards fair pricing’.⁴⁷

Price reduction may occur in various ways: for example, identification of cost-effective medicines on the WHO list provides a focus for national listing and thus engenders economies of scale for procurement; it also increases consumption of the medicines and

⁴² UN Office on Drugs and Crime, *Outcome Document of the 2016 UN General Assembly Special Session on the World Drug Problem* (UNODC, 2016) 2.

⁴³ See High-Level Panel on Access to Medicines (n 5).

⁴⁴ WHO Expert Committee on the Selection and Use of Essential Medicines, ‘The Selection and Use of Essential Medicines’ (WHO Technical Report Series 994, 2015) 2.

⁴⁵ WHO Expert Committee on the Selection and Use of Essential Medicines (n 9) 5. See also WHO Expert Committee on the Selection and Use of Essential Medicines (n 44) 6: ‘it is expected that the addition of these medicines to the EML will support efforts to reduce the prices’.

⁴⁶ See further WHO, *Ten years in public health, 2007–2017: report by Dr Margaret Chan, Director-General, World Health Organization* (WHO, 2017), which estimates that ‘nearly 2 billion people have no access to basic medicines’: 14.

⁴⁷ WHO, ‘Fair Pricing Forum: 2017 Meeting Report’ (2017) WHO/EMP/IAU/2017.10, 7.

therefore reduces price. Additionally (as explored further below), listing will generate pressure for access to medicines such that governments – including those in high-income countries) – will feel both empowered and obliged to bargain with pharmaceutical companies and/or to devise other means to reduce costs, thereby increasing access. Hence, as indicated by the WHO Director of Essential Medicines and Health Products: ‘the Essential Medicine List is one of the first steps in the direction of fair pricing because when we designate a medicine as essential, buyers have some leverage in negotiating for the final purchase price’.⁴⁸

However, the WHO also concedes that, at least in the short term, the high cost of these medicines is likely to inhibit, rather than to enhance, access.⁴⁹ That is, notwithstanding that they have been deemed to be safe, effective and cost-effective, provision of access to these medicines at current prices (for example, the listed drugs for the treatment of hepatitis C cost up to US\$95,000 for a 12 week course of treatment)⁵⁰ is unlikely to be considered a priority for the expenditure of scarce resources: ‘there is an “opportunity cost” of investing in some of these medicines: expenditure may lead to a reduction in the funds available for other interventions’;⁵¹ Although allowance must be made for time-lag in giving effect to WHO recommendations, there is already evidence of difficulty in accessing such medicines. For example, Robertson et al note both that only 16% of 135 countries surveyed included three

⁴⁸ Suzanne Hill, quoted in C. Saez, C ‘New WHO Essential Medicines List: Antibiotics, Hepatitis C, Leukaemia, TB’ (*Intellectual Property Watch*, 6 June 2017) <www.ip-watch.org/2017/06/06/new-essential-medicines-list-antibiotics-hepatitis-c-leukaemia-tb/> accessed 10 May 2018. See further M. McCarthy, ‘What makes an essential medicine?’ (2017) 358 *British Medical Journal* j3044; and a WHO-funded piece of research, which concludes that ‘a wide range of the drugs on the EML can be profitably sold at very low prices in all countries’: A. Hill, D. Barber and D. Gotham, ‘Estimated costs of production and potential prices for the WHO Essential Medicines List’ (2018) 3(1) *BMJ Global Health* e000571.

⁴⁹ WHO Expert Committee on the Selection and Use of Essential Medicines (n 44) 6: ‘prices are likely to be major barriers to access to these medicines’. See also Gray et al (n 29); S. Manikandan, ‘Are we moving towards a new definition of essential medicines?’ (2015) 6 *Journal of Pharmacology and Pharmacotherapeutics* 123.

⁵⁰ Gray et al (n 29) 1601.

⁵¹ WHO Expert Committee on the Selection and Use of Essential Medicines (n 44) 5.

expensive, ‘targeted’ cancer therapies, imatinib, rituximab and trastuzumab, on national lists, and that there is a significant correlation between the number of new cancer medicines nationally listed and gross national income, government health expenditure and numbers of physicians.⁵² Similarly, access to the listed medicines for treatment of multidrug-resistant tuberculosis is extremely low, being estimated at just 5% of eligible patients in March 2017.⁵³

Since states at all levels of development seem certain to face difficulties in affording the expensive treatments recently included in the list, ostensibly there is likely to be an increased incidence of non-compliance with international human rights obligations which relate to access to essential medicines. However, whether this is in fact the case turns upon the precise nature of the obligation which arises under Article 12 ICESCR. The next two sections of this article will explore this issue, before other relevant human rights are considered.

4. Human rights and implementation of the WHO list

The relationship between the WHO list and the human right to access essential medicines under Article 12 ICESCR was examined in the 2006 report of the Special Rapporteur. This stated that:

Guided by the WHO Model List of Essential Medicines, a State is required to prepare a national essential medicines list, by way of a participatory inclusive process. If a State declines to prepare its own national essential medicines list, the WHO model list will apply, subject to any obvious contextual revisions. *A State has a core obligation of immediate effect — not subject to progressive realization — to make available and accessible throughout its jurisdiction the essential medicines on its national list.*⁵⁴

Thus, although General Comment No. 14 had not been wholly explicit on this point,⁵⁵ the work of the Special Rapporteur makes clear that the WHO list acts as a *guide* to national decision-makers, who are expected to develop lists to reflect local health priorities, as

⁵² J. Robertson et al, ‘Essential Medicines for Cancer: WHO Recommendations and National Priorities’ (2016) 94 Bulletin of the World Health Organization 735.

⁵³ Médecins sans Frontières, *Out of Step 2017* (Médecins sans Frontières, 2017).

⁵⁴ HRC (n 1) para. 57. Emphasis added.

⁵⁵ See above, n 2 and accompanying text.

‘implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility’.⁵⁶

The matter was revisited in a subsequent report, published in 2013, which expanded upon the process for development, and content of, national essential medicines lists. These were described as being ‘based on the rationale that a limited range of priority medicines contributes to better health care and optimizes the use of financial resources in resource-limited settings’.⁵⁷ However, the Special Rapporteur acknowledged that the lists functioned as a incentive to cost-containment measures in states at *all* levels of development:⁵⁸ hence, as discussed in the preceding section, ‘resource-limited’ is now best construed as relating also to affordability questions in high-income countries, in addition to those low and middle-income states which have traditionally been the focus of the WHO’s essential medicines strategy.

It may also be noted that the existence of such a list, its scope of coverage, the level of expenditure upon, and the proportion of persons in the population with access to, essential medicines, function as indicators for measurement of a state’s compliance with the right to health by the UN.⁵⁹ Additionally, the WHO has stated that maintenance of a national and/or subnational list is germane to measurement of the proportion of a population with access to affordable medicines and vaccines on a sustainable basis, which is an indicator of compliance with Sustainable Development Goal 3.8, the achievement of universal health coverage.⁶⁰

Most countries (estimated at 86% by the WHO in 2007)⁶¹ have adopted national lists of essential medicines – with some also being compiled at provincial or state level – and in this respect it can be said that the WHO list has ‘gained widespread acceptance... [and] is

⁵⁶ WHO Expert Committee on the Selection and Use of Essential Medicines (n 12) 16.

⁵⁷ HRC, ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines’ (15 May 2013) UN Doc A/HRC/23/42, para. 41.

⁵⁸ *ibid.*

⁵⁹ See UN International Human Rights Instruments, ‘Report on indicators for monitoring compliance with international human rights instruments’ (6 June 2008) UN Doc HRI/MC/2008/3.

⁶⁰ See WHO, ‘World Health Statistics 2016: Monitoring Health for the SDGs’ (2016) 78.

⁶¹ van den Ham, Bero and Laing (n 18) 6.

considered a cornerstone of national medicine policies'.⁶² However, there is frequently significant disparity between national lists and that compiled by the WHO, and the 2013 Special Rapporteur's Report identified a lack of uptake of medicines listed by the WHO on national lists as problematic,⁶³ an observation which is borne out by academic research..⁶⁴ Lack of systematic mechanisms for procurement and supply, poor healthcare infrastructure, and inadequate governmental commitment have been identified as particularly important explanatory factors in this regard,⁶⁵ but it is clear that the cost – and thus, the affordability – of medicines also plays an important role in the choice of medicines listed at national level.

However, notwithstanding the concern expressed by the Special Rapporteur, discrepancies between national lists and the model version published by the WHO do not in themselves amount to violations of the right to access essential medicines. The WHO list merely functions as a guide – offering a definition of medicines which might be classified as essential – and is therefore non-binding. By way of illustration, the list signifies similar clinical performance within a pharmacological class through use of a square box symbol; while the listed medicine is that for which there is best evidence of effectiveness, it is merely representative, and it is accepted that those compiling national lists may select alternatives within the class, for example for reasons of cost.⁶⁶ Furthermore, the selection of medicines at national level should reflect the priority needs of the population; inevitably, burdens of

⁶² IMS Institute for Health Informatics (n 30) 2.

⁶³ HRC (n 57) para. 45.

⁶⁴ See eg H. Coelho et al, 'A critical comparison between the World Health Organization list of essential medicines for children and the Brazilian list of essential medicines (Rename)' (2013) 89 *Journal de Pediatria* 171; A. Tejani and A. Wertheimer, 'International Variations in Essential Medication Lists' (2014) 5 *Innovations in Pharmacy* 147; V. Perumal-Pillay and F. Suleman, 'Quantitative evaluation of essential medicines lists: the South African case study'. (2016) 16 *BMC Health Services Research* 687; A. Rowlands et al, 'WHO and national lists of essential medicines in Mexico, Central and South America, and the Caribbean: are they adequate to promote paediatric endocrinology and diabetes care?' (2016) 1(3) *BMJ Global Health*; Robertson et al (n 52). The matter may also be raised in Concluding Observations issued by treaty bodies: see eg CESCR, Concluding Observations on the combined third and fourth periodic reports of Jamaica, E/C.12/JAM/CO/3-4 (10 June 2013), para. 28(d).

⁶⁵ Chapman (n 33); IMS Institute for Health Informatics (n 30).

⁶⁶ van den Ham, Bero and Laing (n 18) 2.

disease vary across the globe and thus not all medicines contained on the model list will be deemed ‘essential’ in every situation: for example, certain tropical diseases have low prevalence in South Africa, and are therefore not nationally listed.⁶⁷ More controversially, some medicines listed on the WHO list are excluded from national lists for cultural reasons. Thus, emergency contraception, listed by the WHO, has been prohibited or limited in certain Latin American countries, including Honduras and Costa Rica, and courts in Argentina, Chile, Ecuador and Peru have intermittently upheld the legality of such restrictions, notwithstanding the existence of a right to access medicines in such countries.⁶⁸ Similar issues arise with respect to opioid substitutes such as methadone (given criminalization of drug use in some jurisdictions), and medical abortion pills.⁶⁹ Indeed, in the case of the latter, the WHO list contains an explicit rider stating that selection is subject to national law and cultural appropriateness.

By contrast, the 2006 report of the Special Rapporteur specifies that states have an obligation of immediate effect to make available those medicines which are listed on their *national* lists (or where no such list exists, those listed by the WHO). Thus, where a state does not secure accessibility to an essential medicine included on its national list, a *prima facie* violation of the ICESCR occurs, since the state is failing to comply with its ‘minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels’ of the right enshrined in Article 12(2)(d).⁷⁰ The state may be held accountable for its failures to meet such obligations through a variety of mechanisms for accountability, including political, administrative and quasi-judicial, and at national, regional or international levels. However, judicial accountability has proved to be of particular significance. The right to access medicines which are nationally listed as essential but which have nonetheless not been made available to the population has successfully been enforced in court on a number of occasions,

⁶⁷ Perumal-Pillay and Suleman (n 64).

⁶⁸ M. Hevia, ‘The legal status of emergency contraception in Latin America’ (2012) 116 *International Journal of Gynecology and Obstetrics* 87.

⁶⁹ HRC (n 57) para. 41.

⁷⁰ CESCR, General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant) (1990) UN Doc E/1991/23, para. 10. See also A. Yamin, ‘Not Just a Tragedy: Access to Medication as a Right under International Law’ (2003) 21 *Boston University Law Journal* 325, 359.

especially in South America,⁷¹ although other such cases have failed; moreover, most pleadings do not make specific reference to Article 12 and some make reference to other rights, notably the right to life.⁷² Perhaps unsurprisingly, however, many legal challenges seek to facilitate access to medicines *not included* on national lists of essential medicines at all.⁷³

5. The human right to health and extension of the WHO list

The principles outlined in the preceding section provide a basis for analysing the interplay between the expansion of the WHO list to embrace certain high-cost medicines which are not readily affordable, access to which may therefore be limited or denied, and the human right to health.

As noted above, compliance with the content of the WHO list is not in itself a binding obligation under Article 12 ICESCR, although it will apply where no national list is prepared. This would suggest that, states are, in principle, lawfully entitled to *omit* the treatments for cancer, hepatitis B, multidrug-resistant tuberculosis, and prevention of HIV infection specified on the 2015 and 2017 lists from their national lists on grounds of affordability, just as they might any other medicine selected as essential by the WHO. Since the right to access medicines which are not nationally listed is one which, while encompassed by Article 12, is

⁷¹ For discussion, see eg H. Hogerzeil et al, ‘Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?’ (2006) 368 *Lancet* 305; M. Machado et al, ‘Judicialization of Access to Medicines in Minas Gerais state, Southeastern Brazil’ (2011) 45 *Revista de Saúde Pública* 590; J. Biehl, M. Socal and J. Amon, ‘The Judicialization of Health and the Quest for State Accountability: Evidence from 1,262 Lawsuits for Access to Medicines in Southern Brazil’ (2016) 18 *Health and Human Rights* 209.

⁷² Hogerzeil et al, *ibid*.

⁷³ See eg *ibid*; V. Pepe et al, ‘Characterization of Legal Demands for the Supply of “Essential” drugs in the State of Rio de Janeiro, Brazil’ (2010) 26 *Cadernos de Saúde Pública* 461; S. Gloppen and O. Norheim, ‘Litigating for Medicines: How Can We Assess Impact in Health Outcomes?’ in A. Yamin and S. Gloppen, *Litigating Health Rights: Can Courts Bring More Justice to Health?* (Harvard University Press 2011). But cf Biehl, Socal and Amon (n 71).

subject to progressive realisation in accordance with Article 2(1) ICESCR, a state has a putatively lawful justification for lack of availability and access on the basis of limits to its available resources. Given that these medicines are especially expensive, this is a highly pertinent factor.

Nonetheless, as Yamin notes, ‘resource constraints cannot be used as a blanket excuse by governments’.⁷⁴ Article 2(1) obliges a state to take steps towards progressive realisation of the rights protected by the Covenant ‘to the maximum of its available resources’. This means that, first, any wilful refusal to use all available resources to move expeditiously towards provision of such medicines as a dimension of the human right to health would amount to a violation, placing a burden upon the state to demonstrate that it has made every effort to use its available resources.⁷⁵ Secondly, ‘resource availability means that what is required of a developed State is of a higher standard than what is required of a developing State’.⁷⁶ Thus, a justification of scarcity of resources which may be open to a lower or middle-income country is less readily available to the richest nations. Consequently, such states are under enhanced rights-based pressure to ensure access to these expensive medicines, as well as the cheaper essential treatments which, under earlier iterations of the essential medicines concept, it was assumed would be routinely provided. This outcome clearly aligns with the WHO’s current perception of access to medicines as a problem with *global* dimensions, rather than one which is confined to the poorest states.

It should also be noted that denial of access resulting from omission of essential medicine from a national list may be considered more generally to amount to a violation of human dignity as the basis of all human rights.⁷⁷ This is an argument which has been made successfully before national courts in respect of other essential medicines, albeit on relatively few occasions.⁷⁸

⁷⁴ Yamin (n 70) 360.

⁷⁵ CESCR (n 2) para. 47.

⁷⁶ HRC (n 1) para. 55.

⁷⁷ CESCR (n 2) paras. 1, 3.

⁷⁸ As outlined in the preceding section, other bases of challenge in to failure to categorise medicines on national lists may also be available, depending upon whether, and the manner in which, the human right to health (and cognate rights) is given constitutional effect: as noted, courts will not necessarily uphold a rights claim in this context.

By contrast, a decision to *include* the expensive treatments on a national list triggers the core obligation under Article 12.⁷⁹ This obligation is described by General Comment No. 14 as being non-derogable,⁸⁰ although the Committee on Economic, Social and Cultural Rights had originally taken a more lenient position, under which a presumption of failure to comply could be rebutted by demonstration by a state that it had made every effort to utilise all resources which were available to it to satisfy the obligation to provide access to medicines deemed to be essential, and that it had done so as a matter of priority.⁸¹ As Forman et al have noted, there is significant scholarly debate as to whether non-derogability is feasible or practical, suggesting that there remains a need for greater clarity over the role of the core in conceptualising and realising the right to health.⁸²

There is also a more open-ended obligation upon a state to ensure that all existing medicines – *not simply those which are deemed by WHO as essential* – are available and accessible to a population in sufficient quantities so that the state satisfies its human rights requirements to take necessary steps to ensure both ‘the prevention, treatment and control of epidemic, endemic, occupational and other diseases’ and ‘the creation of conditions which would assure to all medical service and medical attention in the event of sickness’ (Articles 12(c) and (d) ICESCR).⁸³ Such an obligation will be stronger in respect of those conditions which contribute significantly to the burden of disease within a particular population.

Arguably, the easiest means by which a state may comply with this limb of the human right to health is to ensure that it provides access, albeit not necessarily through designation on a national list, to those treatments specified by WHO, since these have already been evaluated to be safe, effective, and cost-effective relative to other treatments for the same condition. Doing so will avoid the need for duplication of effort in assessment of the technology; moreover it provides an ‘off-the-peg’ rationale for the choice of a particular treatment over others for the same condition, which may prove especially helpful in securing public acceptance of the expenditure of finite healthcare resources upon the medicine in

⁷⁹ Above n 54 and accompanying text.

⁸⁰ CESCR (n 2) para. 47.

⁸¹ CESCR (n 70) para. 10. See also Yamin (n 70) 359.

⁸² L. Forman et al, ‘Conceptualising minimum core obligations under the right to health: How should we define and implement the “morality of the depths”’ (2016) 20 The International Journal of Human Rights 531.

⁸³ See HRC (n 1) paras. 47-48.

question. Additionally in this manner, therefore, listing of a medicine by WHO, although not *determinative* of decisions on health system coverage which a state must make in order to give effect to its human rights obligations, is nonetheless likely to be of significant *weight*. In this sense, there is an alignment between the WHO list and a rights-based approach to medicines policies and programmes,⁸⁴ even in the absence of the specific obligation which arises through national listing.

There is therefore a strong *incentive*, in which compliance with human rights obligations plays an important part, for states to adopt the high-cost medicines recently listed by the WHO, even if they choose not to include them on a national list. But at least of equal importance is the *pressure* which WHO listing will generate upon governments. WHO literature is quite explicit that ‘the Model List and its supporting documentation serve as a valuable resource for advocacy... at the country level’.⁸⁵ Indeed, it goes so far as to issue a recommendation to NGOs and civil society to ‘support targeted litigation in support of... access to essential medicines’.⁸⁶ This serves to underline the strategic dimension of the WHO list, which was noted previously. One means to secure a reduction in the cost of medicines such as these is to stimulate ‘bottom-up’ movements which, by demanding access, may induce governments (and/or pharmaceutical companies) to implement steps to reduce prices. The inclusion of a treatment on the WHO list provides a visible focus – a rallying-point – for the establishment and activities of such movements.

The earlier campaign for access to antiretroviral treatments for HIV/AIDS provides an instructive illustration in this regard. As Meier and Yamin note,⁸⁷ the development of effective treatment for prolonging the lives of those with HIV/AIDS led to a shift in focus for activists, away from campaigns against discrimination and stigmatization and towards access

⁸⁴ H. Hogerzeil, ‘Essential Medicines and Human Rights: what can they learn from each other?’ (2006) 84 Bulletin of the World Health Organization 371.

⁸⁵ van den Ham, Bero and Laing (n 18) 3.

⁸⁶ H. Hogerzeil and J. Mirza, *The World Medicines Situation 2011: Access to Essential Medicines as part of the Right to Health* (WHO 2011) 9. Note that Hans Hogerzeil was WHO Director for Essential Medicines and Pharmaceutical Policies from 2008 to 2011: see <www.who.int/medicines/areas/nextgen_essentialmeds/next_hogerzeil/en/> accessed 10 May 2018.

⁸⁷ B. Meier and A. Yamin, ‘Right to Health Litigation and HIV/AIDS Policy’ (2011) 39(s1) Journal of Law, Medicine and Ethics 81.

to medicines as a human rights claim under international or domestic law (in the latter instance, most famously manifested in the South African case of *Minister of Health v Treatment Action Campaign (No. 2)*).⁸⁸ Such advocacy and associated litigation had a significant practical impact, ‘transforming aspirational declarations into justiciable obligations and implementing human rights through national policies and programs’ across the world.⁸⁹ The WHO was not in the vanguard of this access movement: indeed, its bureaucratic processes were ‘ironically cast as pathogenic factors in the spread of AIDS itself’,⁹⁰ and thus its listing of antiretrovirals (in 2002) is best seen as a *response* to rights-based advocacy rather than a *stimulus* to it. Nonetheless, as is intended of the 2015 and 2017 extensions, the eventual listing connected to a broader strategy to secure greater transparency of, and ultimately to reduce, prices of these medicines so as to enhance their accessibility and availability.⁹¹

It seems inevitable that advocacy for access to the recently-listed expensive medicines by NGOs and other civil society stakeholders will similarly adopt the discourse and legal form of human rights, with the human right to health at the forefront of such claims. Indeed, examples of this phenomenon are already emerging.⁹²

6. The role of other human rights

Although it is in the context of Article 12 ICESCR that the meaning and content of the right to access medicines has been most comprehensively elaborated, the right also connects to other human rights: this follows from the fact that indivisibility, interdependence and

⁸⁸ [2002] ZACC 15.

⁸⁹ Meier and Yamin (n 87) 81.

⁹⁰ Greene (n 13) 24.

⁹¹ WHA, ‘WHO Medicines Strategy’ (21 May 2001) WHA 54.11, para. 2(2). See also A. Nunn, E. Da Fonseca and S. Gruskin, ‘Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil’ (2009) 4 *Global Public Health* 131.

⁹² See eg Tobeka Daki Campaign for Access to Trastuzumab, ‘Access to Medicines is a Basic Human Right’, letter to UN High Commissioner for Human Rights, (8 March 2017), <www.tac.org.za/files/tobeka-daki-campaign-letter-to-un-human-rights-council-08-03-17.pdf> accessed 31 October 2018; G. Dang, *Know Your Rights: Tuberculosis Prevention, Diagnosis and Treatment* (Treatment Action Group 2018) 2.

interrelatedness amount to central characteristics of the contemporary international human rights framework. Two such rights have been seen as particularly germane in this context: the right to life, and the right to benefit from scientific progress.⁹³ How far, if at all, might those rights be engaged in a situation where a state fails to ensure access and availability of the high-cost medicines which appear in the most recent WHO lists?

6.1 The Right to Life

The right which is most obviously applicable is the right to life, protected in the United Nations system by Article 6(1) of the International Covenant on Civil and Political Rights. Clearly, access to certain medicines may be a necessary condition for survival; thus, policies which restrict or deny such access can, in effect, amount to a deprivation of the right.⁹⁴ Importantly, the UN Human Rights Committee has stated that the right should not be interpreted in a manner restricted to avoidance of actions which directly cause death, but that it also requires positive steps on the part of states, which should include ‘all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics’.⁹⁵ Since the safe and efficacious medicines listed by the WHO for the treatment of hepatitis C, cancer, tuberculosis and prevention of HIV infection will enhance life expectancy (and in the case of the latter three conditions, which can be terminal, may save lives), it would appear that a state which fails to provide access to them is not taking ‘all possible measures’ to give effect to the right to life.

Moreover, the right to life – unlike the right to health – is not subject to progressive realisation, with the consequence that it ‘can be invoked to underscore the urgency of taking immediate measures with respect to providing access to medications’.⁹⁶ Its significance is

⁹³ See S. Marks, ‘Access to Essential Medicines as a Component of the Right to Health’ in A. Clapham and M. Robinson, *Realizing the Right to Health* (Rüffer & Rub 2009).

⁹⁴ Yamin (n 70) 335-36

⁹⁵ HRC, ‘CCPR General Comment No. 6: Article 6 (Right to Life)’ (1982) para. 5.

⁹⁶ Yamin (n 70) 350.

further reinforced by its non-derogability,⁹⁷ and, relatedly, a view of its status as a peremptory norm.⁹⁸

The right to life thus provides an especially potent basis for challenges to limitations on the availability of these medicines, even where such limits are premised upon their unaffordability. However, reflective of indivisibility, such challenges are frequently founded upon more than this right alone. As previously noted, several South American cases concerning access to essential medicines which are based upon domestic constitutional provisions have invoked the right to life and the right to health in conjunction.⁹⁹ high-cost medicines which appear in the most recent WHO lists?

6.2 *The Right to Benefit from Scientific Progress*

While it is readily apparent that a connection exists between the rights to life and health and the right to access medicines, the third human right engaged by the latter is considerably less self-evident, largely because its normative content has been much less comprehensively developed. Article 15(1)(b) ICESCR, which obliges state parties to the Covenant to recognise the right of everyone to enjoy the benefits of scientific progress and its applications, ‘has remained rather obscure and unexplored in human rights discourse’.¹⁰⁰

This is in part because, unlike the right to health, Article 15(1)(b) ICESCR has not been the subject of a General Comment by the Committee on Economic, Social and Cultural Rights, and thus its scope, and the obligations which it imposes, remain somewhat unclear. However, a Report prepared by the Special Rapporteur in the field of Cultural Rights, published in 2012, provides some detail. This notes that the link to the right to health is

⁹⁷ See Article 4(2) ICCPR.

⁹⁸ See W.P. Gormley, ‘The Right to Life and the Rule of Non-Derogability: Peremptory Norms of Jus Cogens’, in R. Betrand, ed., *The Right to Life International Law* (Martinus Nijhoff, 1985).

⁹⁹ See above n 72 and further *Patricia Asero Ochieng v Attorney General* Petition No. 409 of 2009 (High Court of Kenya), para. 56: ‘the right to health, life, and human dignity are inextricably bound’.

¹⁰⁰ L. London, H. Cox, and F. Coomans, ‘Multidrug-Resistant TB: Implementing the Right to Health through the Right to Enjoy the Benefits of Scientific Progress’ (2016) 18 *Health and Human Rights* 25, 26

‘obvious’,¹⁰¹ and identifies a right of access to scientific knowledge, information and advances as the primary component of the normative content of Article 15.

Access may therefore be seen as the ‘touchstone concept’ of the right enshrined in Article 15(1)(b),¹⁰² and since medicines are self-evidently products of scientific progress, it would seem clear that the Article can be read to impose normative obligations upon states in respect of access to medicines. Notably, paragraph 2 requires states parties to take steps necessary for ‘the diffusion of science’, as well as its development. This indicates that the state should make the outputs or applications of scientific knowledge and discovery physically and economically accessible, and since the right accrues to ‘everyone’, must do so in a non-discriminatory manner (as also required by Article 2 ICESCR). Thus, the Special Rapporteur identifies a ‘core principle’ that ‘innovations essential for a life with dignity’ – a description which surely embraces medicines, although this is not explicitly stated – ‘should be accessible to everyone, in particular marginalized populations’.¹⁰³

In part because of the lack of clarity as to its content, the precise role which this right might play in respect of a scenario such as access to costly essential medicines is somewhat uncertain. London, Cox and Foomans argue that the right ‘provide[s] a number of levers *complementary* to right to health claims’.¹⁰⁴ They observe that the right does not create an individual entitlement to development of a new medicine for a particular condition, but that it sets up obligations to create an enabling environment for scientific research, and to provide for diffusion of that research, as well as to abstain from activities which would block or delay

¹⁰¹ HRC, ‘Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: the right to enjoy the benefits of scientific progress and its applications’ (14 May 2012) UN Doc A/HRC/20/26, para. 23. See also Y. Donders, ‘The right to enjoy the benefits of scientific progress: in search of state obligations in relation to health’ (2011) 14 *Medicine, Health Care, and Philosophy* 371.

¹⁰² L. Shaver, ‘The Right to Science and Culture’ (2010) 4 *Wisconsin Law Review* 121, 169.

¹⁰³ HRC (n 101) para. 29.

¹⁰⁴ London, Cox, and Coomans (n 100) 38. Emphasis added. Note also the Venezuelan case of *López and Others v Instituto Venezolano de los Seguros Sociales*, Expediente No. 00-1343, Sentencia No. 487 (Supreme Court of Venezuela, Constitutional Division), 6 April 2001, in which the Supreme Court held that a lack of access to HIV medicines and testing services constituted a violation not only of the right to health, but also of the right to life and of the right to the benefits of science and technology, as enshrined in the state’s constitution.

the availability of new drugs. In this manner, it would appear that Article 15(1)(b) can lend a degree of additional weight to requirements to provide access to the expensive medicines recently added to the WHO list. It seems to entail, as a bare minimum, that national decision-makers should give close consideration to the need to provide coverage of such medicines – whether or not through inclusion on a national medicines list, although this might be bureaucratically the most straightforward means of so doing – since this will facilitate the diffusion of the benefits of scientific progress which such innovative medicines represent, and thus ensure compliance with Article 15. This therefore serves to buttress the incentivisation and pressuring functions of WHO listing which were explored in the preceding section of this article.

It should be noted that Article 15(1)(c) ICESCR also enshrines a right ‘to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’. This appears to set up a problematic tension in the case of medicines, between access to the fruits of scientific progress on the one hand and the rights of those inventing medicines on the other.¹⁰⁵ However, this apparent incompatibility is addressed in various ways. First, the right under Article 15(1)(c) attaches primarily to individuals (‘authors’ or ‘creators’) or, in limited circumstances, groups of individuals or communities, but not entities such as pharmaceutical companies.¹⁰⁶ Secondly, consonant with the principles of indivisibility, interdependence and interrelatedness, the right cannot be viewed in isolation from others protected by the Covenant, hence ‘states parties should therefore ensure that their legal or other regimes for the protection of the moral and material interests resulting from one’s scientific, literary or artistic productions constitute no impediment to their ability to comply with their core obligations in relation to the rights to... health... as well as to enjoy the benefits of scientific progress and its applications’.¹⁰⁷ Thirdly, the Committee on Economic, Social and Cultural Rights makes clear that the scope of protection of the moral and material interests of the author or creator does not necessarily

¹⁰⁵ For a general discussion, see A. Plomer, *Patents, Human Rights and Access to Science* (Edward Elgar 2015).

¹⁰⁶ CESCR, ‘General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1)’ (2006) UN Doc E/C.12/GC/17, paras. 1, 7-8.

¹⁰⁷ *ibid*, para. 35.

coincide with intellectual property regimes, thus envisaging that other forms of protection are permissible and appropriate.¹⁰⁸

It is clear, therefore, that the intellectual property rights of pharmaceutical companies, such as the patents which apply to the medicines recently added to the WHO list cannot be ‘equate[d]... with the human right recognized in article 15, paragraph 1 (c)’.¹⁰⁹ They are to be regarded as legally protected interests of a lower order than human rights such as those to health, life, and enjoyment of the benefits of scientific progress.¹¹⁰ Hence, a state cannot justify a failure to provide access to such medicines merely because rights in intellectual property attach to them.

Of course, it has long been clear, certainly since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),¹¹¹ which came into force in 1995, that the existence of patent protections constitutes a central obstacle to access to medicines. It is beyond the limited scope of this article to explore this issue,¹¹² but it should be briefly noted, , as previously indicated, that a High-Level Panel on Access to Medicines was convened by the UN Secretary-General in 2015 in an attempt to address this ongoing conflict. The Panel’s Report called for full use of the TRIPS flexibilities reaffirmed by the Doha Declaration of 2001,¹¹³ negotiation of a binding research and development convention, regular review by states of access to health technologies in light of human rights obligations, and enhanced transparency (covering measures taken by private sector companies to improve access; costs of research and development, marketing and distribution of health technologies; data on completed and discontinued clinical trials; and patent status).¹¹⁴

¹⁰⁸ *ibid*, paras. 2, 10.

¹⁰⁹ *ibid*, para. 3.

¹¹⁰ Marks (n 97) 89.

¹¹¹ 1869 UNTS 299.

¹¹² For discussion, see eg Pogge. Rimmer and Rubinstein, eds., (n 24); O. Aginam, J. Harrington and P. Yu, eds., *The Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines* (Edward Elgar 2013); J-Y Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge 2016).

¹¹³ WT/Min(01)/Dec/1 (14 November 2001).

¹¹⁴ See High-Level Panel on Access to Medicines (n 5) 9-11.

WHO has indicated that its work programme on access to medicines corresponds with many of these recommendations,¹¹⁵ although the Panel has also been criticised for being insufficiently bold in prioritising the human right to health against trade: for example, it might have recommended (but did not) permanent suspension of TRIPS in respect of essential medicines for low- and middle-income countries.¹¹⁶ An obvious difficulty in pursuing even the modest trajectory mapped by the Panel is that a divide continues to exist between some developed nations and other states as to the relative primacy to be accorded to human rights as against intellectual property considerations in the medicines context.¹¹⁷ Perhaps unsurprisingly, the current US administration has signalled its intention to impede implementation of the Panel's recommendations.¹¹⁸

7. Conclusion

It should be apparent from the preceding discussion that the relationship between the WHO list of essential medicines and the international human rights framework is one of some complexity. However, there is certainly scope for those seeking access to such medicines to frame those demands in terms of failures to comply with human rights obligations, perhaps most potently by way of invocation of a combination of all three rights explored in this article. Since, at least in the short term and even in high-income countries (to which the WHO now intends the list also to be directed), there are likely to be particular difficulties in accessing the expensive medicines recently included on the list, the potential for human rights arguments to be raised in this context appears to have significantly increased.

A possible consequence of the extension of the list to embrace these costly medicines is, therefore, that there will be an increase in health rights-related litigation, particularly at a domestic level in jurisdictions where some degree of constitutional protection is afforded to

¹¹⁵ WHO (n 41), Annex, para. 31.

¹¹⁶ See L. Forman, I. Abdillahi and J. Samuel, 'Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health' (2016) 5 *Laws* 43.

¹¹⁷ See HRC Res 32/15 (18 July 2016) UN Doc A/HRC/RES/32/15.

¹¹⁸ See W. New, 'US Working To Block UN High-Level Panel On Access To Medicines Ideas In Geneva And Capitals' (*Intellectual Property Watch*, 22 January 2018) <www.ip-watch.org/2018/01/22/us-working-block-un-high-level-panel-access-medicines-ideas-geneva-capitals/> accessed 10 May 2018.

the right to health. It is not clear whether WHO has considered this prospect: notably, elsewhere, its regional office for the Americas has expressed disquiet at the tendency of ‘judicialization’ to disrupt the process of rational priority-setting in health care.¹¹⁹ That said, such judicial oversight is, of course, valuable as a means of rendering state actors accountable for actions taken, or not taken, to ensure access, and it can thus contribute to the achievement of the Organization’s goals.

WHO has chosen to list these expensive medicines because there is evidence of their safety, efficacy and their comparative cost-effectiveness as treatments for particular conditions which are regarded as being of international significance. However, the act of listing, with the intention that it will serve to reduce prices in the longer term, also connects to a broader strategy to enhance global access to medicines, given that ‘affordability is the cornerstone of access’.¹²⁰ From the perspective of human rights – especially those dimensions of the right to health which relate to economic accessibility and international obligations to reduce global health inequalities¹²¹ – this is clearly a laudable aim. It remains to be seen how successful it will prove to be.

¹¹⁹ Pan-American Health Organization, ‘Health Technology Assessment and Incorporation into Health Systems’ (16 July 2012) CSP 28/11, para. 5. On the judicialization of health care, see C. Rodriguez-Garavito, ‘The Judicialization of Health Care’, in R. Peerenboom and T. Ginsburg, eds., *Law and Development of Middle-Income Countries: avoiding the middle-income trap* (Cambridge University Press 2014); E. Lamprea, ‘The Judicialization of Health Care: a Global South Perspective’ (2017) 13 *Annual Review of Social Science* 431; and articles in a special section on ‘Judicial enforcement of health rights: focus on Latin America’ (2018) 20 *Health and Human Rights* 67-197.

¹²⁰ WHO (n 46) 15.

¹²¹ See CESCR (n 2) paras. 12(b), 38.